

**REMARKS**

The Office Action of May 9, 2002 presents the examination of claims 1-6. Claim 5 is amended into independent form. No new matter is inserted into the application.

***Interview***

Applicants' representative thanks the Examiner for the interview held on August 9, 2002.

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***Rejection under 35 U.S.C. § 112, first paragraph***

The Examiner rejects claims 1-6 for allegedly containing new matter not described in the specification. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that the negative limitation "excluding the addition of any degradation-inhibiting agents" is not found in the specification. Applicants strongly disagree and point out again to the Examiner the support for the recitation of "excluding the addition of any degradation-inhibiting agents" is indeed found in the specification, for example on page 2, lines 4-6, page 3, lines 6-9, and page 4, lines 18-19.

The Examiner appears to base his assertion on his argument that "a negative limitation requires the highest degree of written description." However, the Examiner cites no authority for his argument, either in U.S. case law or in the Manual of Patent Examining Procedure (MPEP). Applicants therefore respectfully submit that the Examiner that he has no legal authority to make the above statement and haphazardly apply it to the instant case.

Alternatively, Applicants amend claim 5 into independent form, ~~and submit that at least claim 5 should be allowable since~~ "aprotinin" is literally recited on page 4, lines 18-19 of the specification.

For the above reasons, Applicants respectfully submit that the claims fully comply with 35 U.S.C. § 112, first paragraph. Withdrawal of the instant rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

The Examiner maintains the rejection of claims 1-6 under 35 U.S.C. §103(a), for allegedly being obvious over the combination of Lindberg et al. (*Pharmacology & Toxicology*) in view of Clerico et al. (*Clinical Chemistry*). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

In the Reply to the previous Office Action, Applicants argued that both Lindberg et al. and Clerico et al. necessarily required the use of degradation inhibiting agents such as aprotinin or HAS, whereas the present invention excluded the use of such degradation inhibiting agents.

The Examiner was not persuaded by these arguments, and makes two assertions in response. First, the Examiner argues, "No invention is seen in not adding the known inhibitors." Apparently, ~~it is the Examiner's position that since adding the inhibitors in~~ his view is known in the art, then not adding the inhibitors in his view would be obvious. Applicants strongly disagree with the Examiner on this point, and submit that he is not making a proper rejection under 35 U.S.C. § 103. Under 35 U.S.C. § 103, the prior art must disclose or suggest each element of the claims. Here, there is no suggestion or disclosure in the prior to *not* add the inhibiting agents. Thus, the Examiner lacks at least this element of a proper obviousness rejection.

Second, the Examiner argues that the claims are written with open-ended "comprising" terminology. However, the Examiner ignores that the claims, whether or not they recite "comprising," *specifically exclude* degradation inhibiting agents. It is not possible to not exclude the degradation inhibiting agents on one

hand by reciting comprising but exclude degradation inhibiting agents on the other hand by a specific recitation thereof. Applicants respectfully submit that the Examiner that his logic is flawed.

For these reasons, Applicants respectfully submit that the present invention is not obvious over the cited prior art references. Withdrawal of the instant rejection is therefore respectfully requested.

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***Summary***

All of the present claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

If there are any minor matters precluding allowance of the present application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of one (1) month to August 9, 2002, in which to file a reply to the Office Action. The required fee of \$110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

**CLAIM VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

The claims have been amended as follows:

5. (Twice Amended) A [The] method [as claimed in claim 1 or 2] for inhibiting the degradation of mammalian natriuretic peptides in a specimen, comprising:

placing the specimen into a container excluding the addition of any degradation-inhibiting agents, wherein the face coming into contact with the specimen is made of or coated with a material,

wherein said material inhibits the activation of a substance, which substance if not activated, cannot degrade the mammalian natriuretic peptides and is selected from the group consisting of silicone and plastics, and

wherein said specimen does not contain aprotinin.